

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

SHERRY ANN WALKER,
Administratrix of the estate
of Arnold Leroy Walker, Jr.,
and SHERRY ANN WALKER,
Individually,

Plaintiff,

v.

CIVIL ACTION NO. 2:07-00317

MEDTRONIC, INC., and
MEDTRONIC USA, INC.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the court is defendants' motion for summary judgment. (Doc. No. 31.) For the reasons stated below, the motion is denied without prejudice.

I. Factual and Procedural Background

Plaintiff Sherry Walker filed this diversity jurisdiction action on May 18, 2007. (Doc. No. 1.) She asserts that her late husband, Arnold Leroy Walker, Jr., died when his internally-implanted Medtronic SynchroMed EL Infusion Pump malfunctioned. (Id. at 3.) Her complaint asserts three causes of action against defendants Medtronic, Inc., and Medtronic, USA, Inc. (collectively "Medtronic"): negligence (Count One), strict

liability (Count Two), and breach of warranty (Count Three).¹ (Id. at 4-7.) Walker seeks compensatory and punitive damages, attorney's fees, costs, and pre- and post-judgment interest. (Id. at 7.) Among the defenses raised by defendants in their August 1, 2007, answer to the complaint is the argument that plaintiff's claims are preempted by the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act. (Doc. No. 5 at 4; Doc. No. 6 at 4.)

Subsequent to the commencement of this action, the United States Supreme Court of Appeals issued its opinion in Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008), a case addressing the federal preemption argument asserted by defendants. Defendants thereafter filed the instant motion for summary judgment, arguing that there is no issue of material fact remaining as to those of plaintiff's claims that have not been foreclosed by the Riegel case. (Doc. No. 31.) In response, plaintiff contends that, to the extent her theory of recovery survives post-Riegel, she has not had the benefit of sufficient discovery at this stage to enable her to rebut defendants' motion for summary judgment.

¹ In the motion for summary judgment, it was asserted that defendant Medtronic USA, Inc., had no involvement in the design, manufacture, or distribution of the device at issue in this case, and that it is therefore not a proper party. (Doc. No. 32 at 1 n.1.) Plaintiff has made no response to this assertion. Accordingly, the court grants defendants' request that Medtronic USA, Inc., be dismissed from this action.

(Doc. No. 40.) Defendants contend that the affidavits and other documentation provided in support of their motion for summary judgment demonstrate that additional discovery is unnecessary. (Doc. No. 48.)

II. Analysis

With respect to summary judgment, Rule 56 of the Federal Rules of Civil Procedure provides that

[t]he judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.

Fed. R. Civ. P. 56. The moving party has the burden of establishing that there is no genuine issue as to any material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). As was explained in Celotex, "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322.

Once the moving party has met this burden, the burden then shifts to the nonmoving party to produce sufficient evidence for a jury to return a verdict for that party.

The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there

must be evidence on which the jury could reasonably find for the plaintiff. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find, by a preponderance of the evidence, that the plaintiff is entitled to a verdict

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Id. at 250-51. Significantly, "a party opposing a properly supported motion for summary judgment may not rest upon mere allegation or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial." Id. at 256.

Pursuant to Federal Rule of Civil Procedure 56(f),² however, summary judgment may be refused "where the nonmoving party has not had the opportunity to discover information that is essential to his opposition." Anderson, 477 U.S. at 250 n.5 (citing Fed. R. Civ. P. 56(f)). Where the materials sought are the object of outstanding discovery, it is particularly inappropriate to deny a motion under Rule 56(f). Ingle v. Yelton, 439 F.3d 191, 196 (4th Cir. 2006) (citing Strag v. Bd. of Trustees, 55 F.3d 943, 954 (4th

² Rule 56(f) provides that "[i]f a party opposing [a motion for summary judgment] shows by affidavit that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) deny the motion; (2) order a continuance to enable affidavits to be obtained, depositions to be taken, or other discovery to be undertaken; or (3) issue any other just order.

Fed. R. Civ. P. 56(f).

Cir. 1995)). Moreover, "courts should hesitate before denying Rule 56(f) motions when the party opposing summary judgment is attempting to obtain necessary discovery of information possessed only by her opponent." Ingle, 439 F.3d at 196-97 (citing Willis v. Town of Marshall, 426 F.3d 251, 264 (4th Cir. 2005)).

The cases construing Rule 56(f) suggest that the denial of a Rule 56(f) application is generally disfavored where the party opposing summary judgment makes (a) a timely application which (b) specifically identifies (c) relevant information, (d) where there is some basis for believing that the information sought actually exists.

Visa Int'l Serv. Ass'n v. Bankcard Holders of Am., 784 F.2d 1472, 1475 (9th Cir. 1986), *quoted in* Ingle, 439 F.3d at 196.

At issue in Riegel was the preemption provision of Section 360k(a) of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act as applied to medical devices that have received premarket approval from the Food and Drug Administration ("FDA").³ In affirming the opinion of the Second Circuit Court of Appeals, the Riegel court held that "[s]tate requirements are

³ The preemption provision states as follows:

(a) General Rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --

- (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a).

pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." Riegel, 128 S. Ct. at 1011 (quoting 21 U.S.C. § 360k(a)(1)).

In agreement with the Second Circuit, however, the Supreme Court limited its preemption analysis to those cases in which liability is alleged despite adherence to the standards on which the device's premarket approval was based. "Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Riegel, 128 S. Ct. at 1011.

Although the claims set forth in plaintiff's complaint are not explicitly premised on a violation of the terms of the infusion pump's premarket approval, plaintiff has made clear that she wishes to pursue such a theory of recovery. (Doc. No. 40 at 9-13.) Additionally, she details several discovery matters yet to be resolved, including her review of the extensive terms of the premarket approval.⁴ (Id. at 11-12.) Citing the affidavits

⁴ The progression of discovery in this case has been affected by matters outside the parties' control. In the court's February 6, 2008, opinion denying defendants' motion to stay, the court directed the magistrate judge to enter an amended scheduling order to account for any delay occasioned by the Supreme Court's ruling in Riegel. (Doc. No. 27 at 5.) Due to court oversight, however, the amended scheduling order was never entered. (See Doc. No. 41.) Subsequently, the court granted the

submitted in support of their motion, defendants rejoin that the pump fully complied with the standards of the FDA's premarket approval, and conclude that the court should grant summary judgment in their favor without further discovery. (Doc. No. 48 at 4-6.)

Where the key issue of material fact - whether the infusion pump complied with the terms of its premarket approval - has not been fully explored through the discovery process, the court is unable to grant summary judgment. Contrary to plaintiff's assertion (Doc. No. 40 at 8-9), however, the complaint does not adequately allege the type of claim which might survive Riegel. Accordingly, the court hereby puts plaintiff on notice that it will entertain a motion to amend the complaint in order to correct this deficiency. See Stevens v. Pacemaker, Inc., No. 3:07-cv-3812, 2008 U.S. Dist. LEXIS 26880, at *3-4 (D.S.C. Apr. 1, 2008) (dismissing case for failure to amend complaint to allege the "narrow category of claim which might survive Riegel"). Because it remains to be seen whether plaintiff will be able to rebut defendants' assertion that the device in question fully complied with its premarket approval, the court denies defendants' motion for summary judgment without prejudice.

parties' joint motion for a stay of discovery pending resolution of the defendants' motion for summary judgment. (Doc. No. 53.)

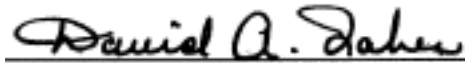
III. Conclusion

For the reasons set forth above, the court hereby **DENIES** defendants' motion for summary judgment **WITHOUT PREJUDICE** (Doc. No. 31), **DISMISSES** defendant Medtronic USA, Inc., and **NOTIFIES** plaintiff that it will entertain a motion to amend the complaint as described above.

The Clerk is directed to forward a copy of this Memorandum Opinion and Order to all counsel of record.

It is **SO ORDERED** this 9th day of September, 2008.

ENTER:

A handwritten signature in black ink, appearing to read "David A. Faber", is written over a horizontal line.

David A. Faber
United States District Judge